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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,500	11/29/2000	David A Cheresh	TSRI 651.1	5356

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OLSON & HIERL, LTD.
20 NORTH WACKER DRIVE
36TH FLOOR
CHICAGO, IL 60606

EXAMINER	
SCHNIZER, RICHARD A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/701,500	CHERESH ET AL.	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,14-16,33 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,14-16,33 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on *29 November 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

An amendment was received and entered on 1/8/04.

Claims 2, 3, 12, and 13 were canceled.

Claims 1, 4,14-16, 33, and 34 remain pending and under consideration in this Office Action.

Rejections Withdrawn

The rejections of claims 1, 4, and 14-16 under 35 U.S.C. 112, first and second paragraphs are withdrawn in view of Applicant's amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Kato et al (FEBS Lett. 411:317-321, 1997).

Kato teaches a non-viral vector (pOPI3) comprising a human c-Src cDNA. It is noted that, in order to be enabled, the claimed composition must be capable of stimulating angiogenesis in a tissue to which it is directly applied. The instant specification provides no guidance as to what is the minimum amount of the composition which is required to achieve this effect. Because the claimed composition

and that of Kato are structurally indistinguishable, the composition of Kato is considered to be capable of stimulating angiogenesis to a tissue in which it is directly applied, absent evidence to the contrary. Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an Applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke, 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Thus Kato anticipates the claims.

One might argue that the claimed compositions distinguish over Kato because they comprise packaging material and a label reciting an intended use. However, it is well settled that the application of particular printed matter to an old article cannot render the article patentable. In re Thomas J. Dixon, 18 C.C.P.A. (Patents) 711, 44 F.2d 881, 7 USPQ 209 ; In re Robert C. Russell, 18 C.C.P.A. (Patents) 1184, 48 F.2d 668, 9 USPQ 181 ; In re Reeves, 20 C.C.P.A. (Patents) 767, 62 F.2d 199, 16 USPQ 110 ; In re McKee, 20 C.C.P.A. (Patents) 1018, 64 F.2d 379, 17 USPQ 293 ; In re Hansen, 33 C.C.P.A. (Patents) 979, 154 F.2d 684, 69 USPQ 332 . Accordingly, the mere labeling of an old composition as a product capable of a new use does not make it a new or

different composition within the meaning of the patent statutes. The rejected claims represent an attempt to patent an old product on the basis of a statement that it is intended for a new use. Whether the statement of intended use appears merely in the claim or in a label on the product is immaterial so far as the question of patentability is concerned. Thus, Kato anticipates the claims.

Response to Arguments

Applicants arguments filed 1/8/04 have been considered as the may apply to the grounds of rejection set forth above, but are unpersuasive.

Applicant argues at pages 5 and 6 of the response that it is incorrect to assert that the application of particular printed matter to an old article cannot render the article patentable, and relies for support on the findings of the court in *In re Gulack* and *In re Miller.* Applicant is correct that *In re Gulack* and *In re Miller* support the position that printed matter can lend patentable weight to a claim, and it is acknowledged that the claims must be viewed as a whole as per the Patent Act of 1952. However, the situations in *Gulack* and *Miller* are not analogous to the instant situation, and the claims have been considered in their entirety. In both *Gulack* and *Miller*, the printed matter changed the intrinsic qualities of the material to which it was applied. In other words, the functions of the claimed devices depended on the printed matter itself, which was part of the substrate. That is, the printed matter was part of the hat in *Gulack*, and part of the cup in *Miller,* and in each case the printed matter altered both the structure and the function of the material to which it was applied. In both cases, without the printed

material, the substrates lose their function. In contrast, the printed matter in the instant case is merely a label that indicates that the claimed nucleic acid may be used for a particular purpose, but the label itself does not confer any new or different functionality on the claimed nucleic acid, nor does it change the structure of the nucleic acid. In fact, the nucleic acid retains its full functionality absent the recited printed material.

Regarding the issue of whether or not the claims were considered in the entirety, It is well settled that an intended used does not impart patentable weight to a claimed product, and in this case the claimed label is nothing more than a statement of intended use. In the opinion text of *In re Haller*, 73 USPQ 403 (CCPA 1947), the court stated "[w]hether the statement of intended use appears merely in the claim or in a label on the product is immaterial so far as the question of patentability is concerned." See also MPEP 2111.02 which states:

> Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. **If the prior art structure is capable of performing the intended use, then it meets the claim.** In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459, (CCPA 1963).

Emphasis added. In the instant case, there is no difference in the structure of the nucleic acid in the cited art, and the structure of the nucleic acid in the claimed composition. The only difference is the presence of a label stating an intended use. Clearly, the nucleic acid in the cited prior art is capable of performing the intended use recited on the claimed label, so the claimed article of manufacture is not patentable over the prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kato et al (FEBS Lett. 411:317-321, 1997), in view of Boyse et al (US Patent 5,004,861, issued 4/2/1991).

Kato teaches a method in which expression vectors comprising a human c-Src cDNA are used to stably transfect cultured cells for the purpose of studying cellular metabolism. The cells were transfected by electroporation.

Kato does not teach a liposome or a viral vector.

Boyse teaches methods of making stably transfected cells with genes. At paragraph 148 of the detailed description, Boyse notes that numerous techniques are known in the art for the stable introduction of foreign genes into cells, and further states:

> Techniques which may be used include but are not limited to chromosome transfer (e.g., cell fusion, chromosome-mediated gene transfer, micro cell-mediated gene transfer), physical methods (e.g., transfection, spheroplast fusion, microinjection, electroporation, liposome carrier), viral vector transfer (e.g., recombinant DNA viruses, recombinant RNA viruses) etc. [citation omitted].

Thus Boyse teaches that electroporation, liposome-mediated transfection, and virus-mediated transfection are interchangeable for the purpose of delivering genes to cells. MPEP 2144.06 indicates that when it is recognized in the art that elements of an invention can be substituted, one for the other, while retaining essential function, such elements are art-recognized equivalents. An express suggestion to substitute one

equivalent component or process for another is not necessary to render such substitution obvious. In re Fout, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). For these reasons it would have been obvious to one of ordinary skill in the art at the time of the invention to use liposomes to transfer into cells the human c-src expression vector of Kato. Similarly, it would have been obvious to construct and use a viral vector comprising the human c-Src cDNA.

Thus the invention as a whole was prima facie obvious.

Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kato et al (FEBS Lett. 411:317-321, 1997), in view of Boyse et al (US Patent 5,004,681, issued 4/2/1991) and GenBank Accession No. X59932.

The teachings of Boyse and Kato are summarized above, and render obvious compositions comprising a human c-Src expression vector associated with liposomes, and a viral expression vector encoding human c-Src.

Kato is silent as to the sequence of the human c-src encoded by the cDNA.

GenBank Accession No. X59932 teaches a nucleic acid encoding a human c-Src polypeptide having the sequence of SEQ ID NO:5.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use in the invention of Kato the c-Src sequence disclosed in GenBank Accession No. X59932. The essential feature of the cDNA of Kato is that it encoded a human c-SRC with kinase activity. The nucleic acid of GenBank Accession No. X59932 encodes a human c-Src kinase. As such, these nucleic acids would be

considered by those of ordinary skill in the art to be interchangeable in the invention of Kato, and so they are equivalents. MPEP 2144.06 indicates that when it is recognized in the art that elements of an invention can be substituted, one for the other, while retaining essential function, such elements are art-recognized equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. In re Fout, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Furthermore, MPEP 2144.07 indicates that the selection of a known material based on its suitability for its intended use supports the determination of prima facie obviousness. See also Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945).

Thus the invention as a whole was prima facie obvious.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, John Leguyader, be reached at 571-272-0760. The official central fax number is 703-872-9306. Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 571-272-0564.

Richard Schnizer, Ph.D.